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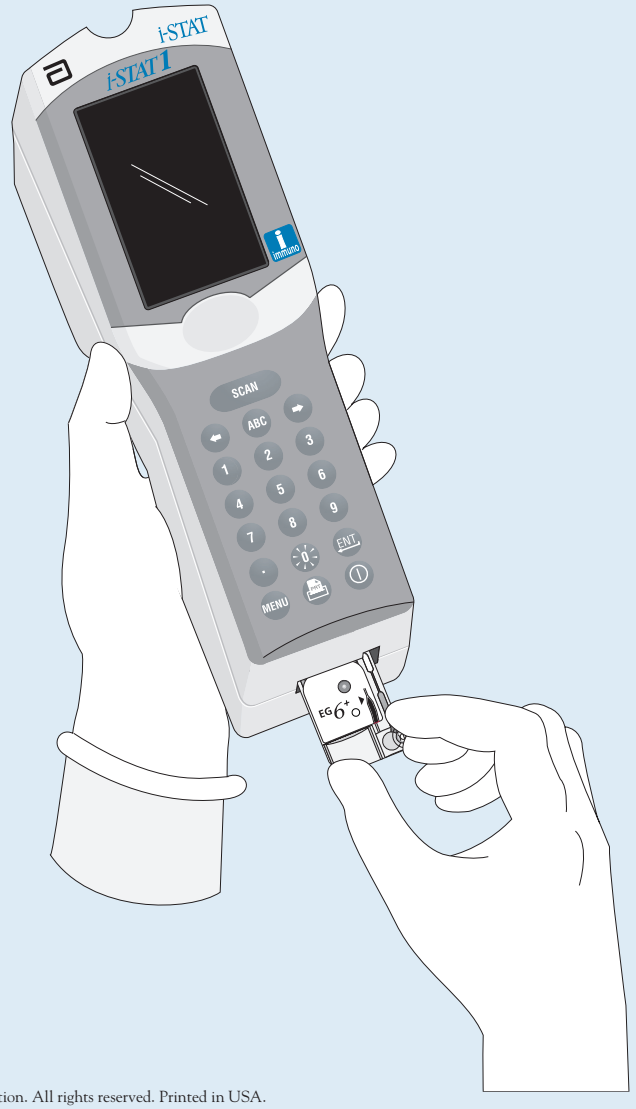
# i-STAT®1 User Guide




i-STAT

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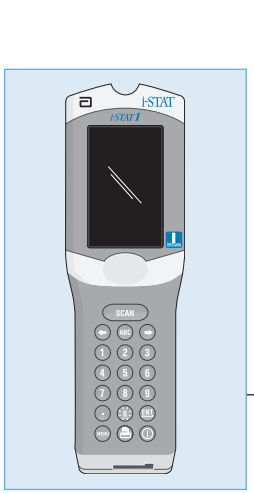
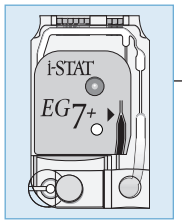
# System Components

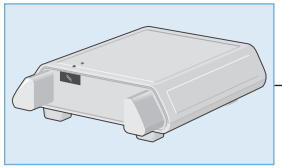



*i-STAT 1 Analyzer*

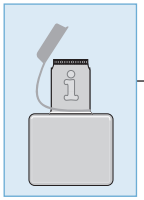



*i-STAT cartridge*

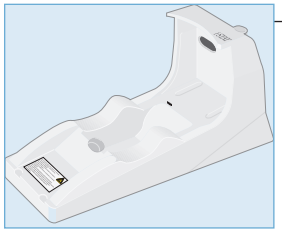
*Foil Packet containing the MediSense® Precision PCx™ or PCx™ Plus Glucose Test Strip*



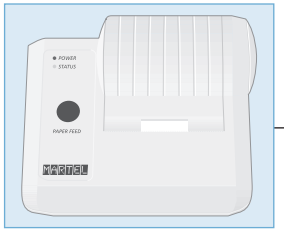
*i-STAT 1 Downloader*



*Electronic Simulator*



*i-STAT 1 Downloader/Recharger*




*Martel Printer*

IVD For *in vitro* diagnostic use.

See System Manual for instructions.

Intended Use: The i-STAT®1 Analyzer is intended for use with i-STAT cartridges for the *in vitro* quantification of various analytes in whole blood and with the Abbott Medisense® Precision PCx™ and PCx™ Plus Blood Glucose Test Strips for the *in vitro* quantification of glucose in whole blood.

## *Quality Check Messages and Codes*

| Message | Cause | Action |
|---|---|---|
| Date Invalid, Check Clock | Date outside six month lifetime of software. | Select 5-Clock Set from Administration Menu. (Password protected.) |
| Dead Batteries, Replace Batteries | Insufficient power to complete a test cylce. | Replace disposable batteries or recharge the rechargeable battery. |
| Temperature Out of Range, Check Status page | Temperature outside operating range of 16 to 30 °C. | Check analyzer temperature by pressing 1 for Analyzer Status under the Administration Menu. Move analyzer to warmer area if below operating range or to cooler area if above the range. |
| Invalid or Expired CLEW | Software expired or corrupt. | Verify that the analyzer's date is correct. Change software if expired. Update again if not expired. |
| Analyzer Interrupted, Use Another Cartridge | Last cartridge run not completed. | Check the battery pack inserted properly. Check for Low Battery startup warning. |
| Cartridge Error | Usually problem with sample or cartridge filling. | Use another cartridge. If same code repeats more than twice, try another analyzer. |
| Cartridge Preburst | Calibrant pack burst before cartridge inserted into analyzer. | Use another cartridge - do not press on center of cartridge. Check that cartridges have not been frozen. |
| Unable to Position Sample | Cartridge not sealed. Clot in sample. Aberrant cartridge. | Use another cartridge. |
| Sample Positioned Short of Fill Mark | Cartridge underfilled. | Use another cartridge - fill to Fill Mark. |
| Sample Positioned Beyond Fill Mark | Cartridge overfilled. | Use another cartridge - do not fill beyond Fill Mark. |
| Test Cancelled by Operator | User did not respond to mandatory prompt before analyzer time out. | No action required. |
| Cartridge Type Not Recognized | Software does not recognize cartridge. | Update software. Check to see if cartridges are expired. |
| Analyzer Error, Use Electronic Simulator | Analyzer detects problem from which it is likely to recover. | Insert the Electronic Simulator. If PASS, continue to use analyzer. |
| Analyzer Error, See Manual | Analyzer detects problem from which it may not recover. | Insert Electronic Simulator. If PASS, insert a cartridge with sample or control. If the code does not reappear, continue to use analyzer. |
| Strip Error | A wet strip inserted, strip pulled out during testing cycle, temperature of analyzer exceeds operation temperature for strip testing | Repeat test using proper procedure. Check Analyzer Status under the Administration Menu for analyzer temperature. |
| No display | Disposable batteries dead or rechargeable battery fully discharged. Keypad not responding. Start switch broken. | Change disposable batteries or recharge battery. If still no display, call Support Services. |
| Cartridge Locked does not disappear after test cycle completed | Dead battery(s). Mechanical problem. | Wait until analyzer turns off. Turn analyzer on. If resets, remove cartridge. If not, change or recharge battery(s) and turn analyzer on. |

# Blood Collection

## *Acceptable Samples for Cartridges*

- Arterial: Plain syringe, heparinized syringe labeled for analytes to be tested and filled to capacity, or syringe with minimum volume of heparin to prevent clotting (10 U/mL of blood). For ionized calcium, use balanced heparin syringes. Mix heparinized syringes by rolling between palms for at least 5 seconds in 2 directions, then invert the syringe repeatedly for at least 5 seconds. Test for lactate immediately. Test for other analytes within 10 minutes.
  - Avoid drawing air into syringes for blood gas and ionized calcium tests.
  - If not tested immediately, remix and discard 2 drops of blood before filling cartridge.
  - Do not use iced samples.
- Venous: Collection tube with lithium or sodium heparin filled to capacity and mixed by gentle inversion at least 10 times. Test within 10 minutes.
  - Do not leave tourniquet on for more than 2 minutes.
  - Do not draw above an I.V.
- Skin puncture: Lithium heparin capillary tubes for testing all analytes but ionized calcium. For all analytes including ionized calcium, use plain or balanced heparin capillary tubes. Test immediately.
  - Allow alcohol to dry over puncture site before collecting sample.
  - Do not "milk" finger or heel while collecting sample.
- Coagulation Tests:
  - The ACT test can be performed using venous or arterial samples, while the PT/INR test can be performed using capillary or venous samples.
  - Use plain plastic syringes or plastic evacuated tubes with no anticoagulant, activators, or serum separators.
  - Test sample immediately upon draw.
  - Some experts recommend drawing and discarding a sample of at least 1 ml prior to drawing samples for coagulation testing.
  - If a second measurement is needed, draw a fresh sample.
  - For In-dwelling line testing for ACT:
    a. Fluid drip through the line must be discontinued.
    b. Withdraw 2 ml of blood into a syringe and discard it.
    c. Withdraw the sample into a fresh plastic syringe with no anticoagulant, and test immediately.
  - For extracorporeal line testing for ACT:
    a. Flush the extracorporeal blood access line by withdrawing 5 ml of blood into a syringe and discard the syringe.
    b. Withdraw the sample into a fresh plastic syringe with no anticoagulant, and test immediately.
  - For skin puncture testing for PT/INR, see the section on "Patient Test Procedures".

- Troponin I/cTnI Tests
  - cTnI cartridges require the use of either:
    a. heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin, or
    b. non-heparinized whole blood or plasma samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives.
  - The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phophatase, resulting in decreased cTnI readings.
  - Capillary tubes and direct skin punctures (e.g. fingersticks) should not be used with the cTnI cartridge.
  - Samples should not be used unless the blood collection tube is filled at least half full.

### *Acceptable Samples for PCx and PCx Plus Glucose Test Strips*

- Arterial and venous: Syringe or tube with lithium heparin, sodium heparin or EDTA. Test within 30 minutes.
- Skin puncture: direct application of sample to test strip or capillary tube with lithium heparin, sodium heparin or EDTA. Test immediately.

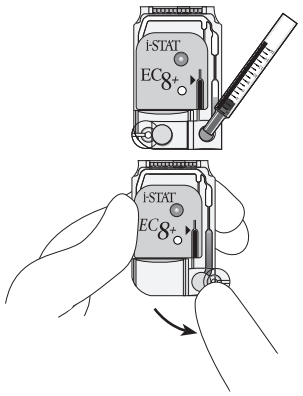
## Limitations

Interfering substances in the patient's sample may cause an increase or decrease in a result. Refer to the Cartridge and Test Information Sheets and Technical Bulletins for substances and/or conditions that may interfere with cartridge tests and to section 13 of the i-STAT 1 System Manual for causes of lower or higher than expected glucose results when using the tests strips.

## Patient Test Procedures

### *Cartridge Test Procedure*

1. Remove cartridge from pouch. Handle a cartridge by its edges. Avoid touching the contact pads or exerting pressure over center of cartridge.
2. Following thorough mixing of the sample, direct syringe tip, pipette tip or capillary tube into the sample well. Dispense sample until it reaches the fill mark on the cartridge.
3. Fold the snap cover over the sample well until it snaps into place. Press on round tab, <u>not</u> over sample well.
4. Insert cartridge into cartridge port. For ACT and PT/INR cartridges, keep analyzer in a horizontal position. Do not attempt to remove cartridge while Cartridge Locked message is displayed.




### *Replacing Paper in the Martel Printer*

1. Squeeze the front and back of the paper cup to open.
2. Remove remaining paper by pressing the Paper feed button. Do not pull paper through printer mechanism.
3. Reel off a few centimeters of paper from the new paper roll and check that the end has a clean straight edge.
4. Slide the leading edge of the paper through the paper entry slot until you feel resistance. Paper feeds from underneath the roll.
5. Press the Paper Feed button and feed the paper through the printer mechanism.
6. Keep the Paper Feed button depressed until the paper passes through the paper exit slot.
7. Sit the new paper roll in the paper cup and close the lid.

## Troubleshooting

### *Unexpected Results*

When results do not reflect the patient's condition, repeat the test using a fresh cartridge and sample. If results are still suspect, test the lot of cartridges in use with i-STAT control solutions. If the controls are in range, there may be an interfering substance in the sample. Check the Cartridge and Test Information sheets for the test in question. Test by another method to verify the result. If the controls are out of range there may be a problem with the cartridge lot number. Use another lot number or repeat the test using another method, and refer to Support Services Information in the Troubleshooting section of the i-STAT 1 System Manual.

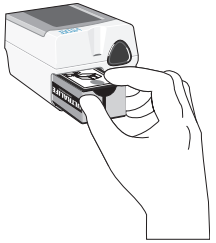
### *Startup Messages*

The analyzer performs self-checks when it is turned on. If a condition that should be corrected in the near future, but that will not affect results, is detected, a warning is displayed. The operator presses the 1 key to access the Test Menu. The analyzer can be customized to lock out the operator until the corrective action is taken.

| Message | Action |
|---|---|
| Electronic Simulator Test Required | Insert Electronic Simulator. |
| PCx Glucose Strip Control Required | Test controls. |
| Stored Memory Low | Place analyzer in Downloader. |
| Stored Memory Full | Place analyzer in Downloader. |
| Upload Required | Place analyzer in Downloader. |
| Battery Low | Replace batteries or recharge battery. |
| CLEW Expiring, Upgrade Required | Upgrade software. |

# Hardware Procedures

## *Replacing Batteries*



1. Slide the battery compartment door off.
2. Tilt the analyzer slightly to slide out the battery carrier.
3. Remove the old batteries from the carrier and replace with 2 new 9V lithium batteries.
4. Insert the carrier back into the compartment – label facing up and electrical contacts first.
5. Slide the battery compartment door into place.

## *Charging the Rechargeable Battery*

Placing an analyzer in a Downloader/Recharger will automatically initiate recharging of the rechargeable battery. The indicator light on top of the Downloader/Recharger will be green (trickle charge), red (fast charge), or blinking red (fast charge pending) when an analyzer with a rechargeable battery is placed in the Downloader/Recharger.

No damage will be caused if an analyzer with disposable batteries installed is placed in the Downloader/Recharger.

## *Charging Rechargeable Battery in External Recharge Compartment*

Placing a rechargeable battery into the recharging compartment will automatically initiate trickle recharging. The indicator light near the recharging compartment will be green when a rechargeable battery is placed in the compartment.

| STEP | ACTION |
|---|---|
| 1 | The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger. With the label with the Downloader facing up and the electrical contact end of the pack facing the contacts in the battery compartment, insert the pack into the compartment as shown on the label. |
| 2 | To remove the battery after it is charged, back the pack out of the compartment. |

Full recharge from a discharged state takes approximately 40 hours.

## *Caution*

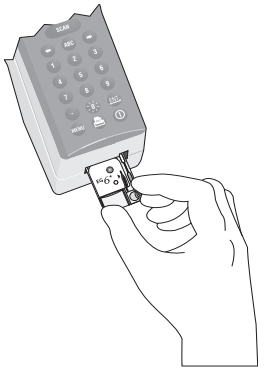
If you are using rechargeable batteries, use only rechargeable batteries and recharging equipment supplied by your i-STAT distributor. Other batteries and rechargers may affect test results and pose other hazards to operators and patients.

## *Cleaning the Analyzer and Downloader*

Clean the display and case with a gauze pad moistened with a mild non-abrasive cleaner, detergent, soap and water, alcohol or 10% bleach solution. Rinse with another pad moistened with water and dry.

5. Scan or enter operator ID. Repeat if prompted.
6. Scan or enter patient ID. Repeat if prompted.
7. Select tests to be reported if prompted.
8. Enter sample type and blood gas parameters on chart page if applicable.
9. View results on analyzer's display.
10. Enter Comment Code if prompted.
11. Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.

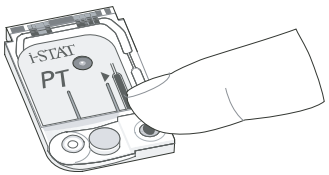
## *Cartridge Test Procedure - Information First*



1. Press the On/Off (⏻) key to turn analyzer on.
2. Press 2 for i-STAT Cartridge from the Test Menu.
3. Scan or enter operator ID. Repeat if prompted.
4. Scan or enter patient ID. Repeat if prompted.
5. Remove cartridge from pouch. Handle a cartridge by its edges. Avoid touching the contact pads or exerting pressure over center of cartridge.
6. Following thorough mixing of the sample, direct syringe tip, pipette tip or capillary tube into the sample well. Dispense sample until it reaches the fill mark on the cartridge.
7. Fold the snap cover over the sample well until it snaps into place. Press on round tab, <u>not</u> over sample well.
8. Insert cartridge into cartridge port. For ACT and PT/INR cartridges, keep analyzer in a horizontal position.
9. Select tests to be reported if prompted.
10. Enter sample type and blood gas parameters on chart page if applicable.
11. View results on analyzer's display.
12. Enter Comment Code if prompted.
13. Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.

## *PT/INR (Prothrombin Time) Cartridge Test Procedure*

### *Caution*




The i-STAT PT/INR cartridge is designed to accept a sample between 20 and 45 microliters. A single drop of blood from either a finger puncture or as formed at the tip of a syringe will typically be within this range. If a larger volume is delivered to the sample well, use caution when closing the cartridge as excess blood may be expelled from the cartridge.

## *Skin Punctures*

1. Remove cartridge from foil pouch and place the cartridge on a flat surface.
2. Prepare lancet device and set aside until needed.
3. Clean and prepare the finger to be sampled. Allow finger to dry thoroughly before sampling.
4. Prick the bottom side of the fingertip with the lancet device.
5. Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood. *Avoid strong repetitive pressure ("milking") as it may cause hemolysis or tissue fluid contamination of the specimen.*
6. Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
7. Apply sample until it reaches the fill mark indicated on the cartridge.
8. Fold the sample closure over the sample well.
9. Press the rounded end of the closure until it snaps into place.

**Note:** To further simplify the sample application into the test cartridge, it is possible to bring the cartridge to the finger for easier application. Do ensure that the instrument remains on a flat vibration-free surface for testing.

## *cTnI (Troponin I) Cartridge Test Procedures*

The i-STAT cTnI Cartridge can only be used with the i-STAT 1 Analyzer bearing the symbol. The analysis time for the cTnI cartridge is 10 minutes.

Before testing cTnI cartridges on the i-STAT 1 Analyzer, the analyzer must be customized through the Central Data Station (CDS) or through the analyzer's Customization menu for the following option(s):

1. Cartridge Barcode Required, or
2. Cartridge Information First Required AND Cartridge Lot Number Required.

## *cTnI (Troponin I) Cartridge Test Procedure (Non-Information First Customization)*

1. Remove cartridge from portion pack. Do not immediately dispose of the portion pack, as the cartridge lot number listed on it will be scanned into the analyzer during the testing procedure. Handle the cartridge from its edges. Avoid touching the contact pads or exerting pressure over the center of the cartridge.
2. Following thorough mixing of the sample, direct the transfer device (either syringe tip or pipette tip) into the inlet port. Apply a single drop of sample to the inlet port. If the cartridge fill is incomplete as seen via the fill indicator on the cartridge label, apply a second small drop until the sample reaches the fill mark.
3. Close the cTnI cartridge:
   a. first anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cTnI cartridge from its side edges away from the sample inlet.

*Procedure*

1. Turn the analyzer on and press the Menu key to access the Administration Menu.
2. Press the 3 key for Quality Tests.
3. Press the 1 key for Control.
4. Press the 1 key for i-STAT Cartridge.
5. Scan or enter Operator ID.
6. Enter the control lot number.
7. Enter the cartridge lot number.
8. Fill a cartridge with the control and close the cover.
9. Insert the cartridge into the cartridge port.
10. Enter chart page information if applicable.
11. View results on analyzer's display.
12. Remove and discard cartridge when Cartridge Locked message disappears.
13. Press the 1 key for Test Options on the results page and press 1 for Next Level if testing another level of control.

## *Test Strip*

- Analyze Low and High Precision Control Solutions when a new lot number of test strips is opened.
- Analyze the Low and High Precision Control Solutions using the test strip lot number in use on a daily basis.
- Analyze control solutions when test strip glucose result is questioned, when diabetes medication plan is adjusted, when strips have been exposed to temperatures outside the storage conditions.
- Control ranges are programmed into the analyzer when the test strip lot number is scanned or entered into the analyzer and control results will be displayed with the acceptable ranges as well as Pass or Fail.

*Procedure*

1. Turn the analyzer on.
2. Press the 3 key for PCx Glucose Strip.
3. Press the 2 key for Control.
4. Scan or enter Operator ID.
5. Scan or enter Low Level Control lot number.
6. Scan or enter test strip lot number.
7. Open foil test strip packet and remove test strip.
8. Insert into test strip port.
9. Apply control solution.
10. Enter chart page information if applicable.
11. View results on analyzer's display. Enter Comment Code if applicable.
12. Remove strip.
13. Press 1 for Test Options and 1 for Next Level if testing another level of control.

# Quality Assurance

## *Analyzer*

*Electronic Simulator*

Perform an electronic check on each analyzer in use once a day with either the internal or external Electronic Simulator or as needed for regulatory compliance. The internal simulator check is initiated, every 24 hours or according to a customized schedule, when a cartridge is inserted into the cartridge port. If the internal simulator result is PASS, the cartridge test proceeds and the simulator results are stored. If FAIL is displayed for the internal simulator, reinsert the cartridge or use an external simulator. The external simulator check is performed as follows:

1. Turn the analyzer on.
2. Press the Menu key to access the Administration Menu.
3. Press the 3 key for Quality Tests.
4. Press the 4 key for Simulator.
5. Scan or enter Operator ID.
6. Enter the Simulator ID (serial number).
7. Insert the simulator into the cartridge port.
8. View results on analyzer's screen.
9. If PASS is displayed, continue to use the analyzer.
10. If FAIL is displayed for the external simulator, reinsert the simulator.

If FAIL is displayed a second time, do not use the analyzer and contact the Point of Care Coordinator.

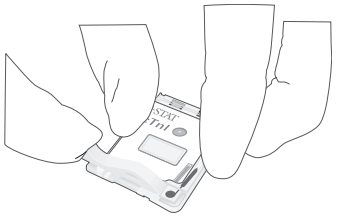
*Thermal Probes and Room Temperature Checks*

See System Manual for these quality assurance procedures that are performed once or twice per year.

## *Cartridge*

- Check temperature strip enclosed with each shipment of cartridges. If the windows are clear or if the A window is blue, or the 1 window is red, the cartridges should be accepted. If the B, C or D windows are blue, or the 2,3, or 4 windows are red contact Support Services (see System Manual).
- Verify the integrity of a new shipment of cartridges, on receipt, by analyzing 2 levels of i-STAT controls and Hematronix Meter Trax controls for hematocrit using any analyzer that has passed the Electronic Simulator test and a representative sample of the lot(s) of cartridges received. Use expected values published in the fluids' package inserts to verify the integrity of the cartridges.
- Verify that the storage conditions listed above have been maintained.

b. use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well. *Note: When sliding the closure clip, the index finger of that same hand should not be placed directly across from the thumb, as this could result in the sample being pushed onto the user's glove. This index finger should be placed just above the position of the sliding clip during closure or not used at all.*



4. Insert the cartridge into the cartridge port. Do not attempt to remove the cartridge while the Cartridge Locked message is displayed.
5. Scan the Cartridge Lot number from the cartridge portion pack.
6. Scan or Enter Operator ID Repeat if prompted.
7. Scan or Enter Patient ID. Repeat if prompted.

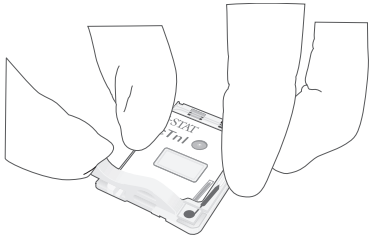
   *The analyzer must remain on a level surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.*
8. Select tests to be reported, if prompted.
9. Enter sample type on chart page if applicable.
10. View results on analyzer's display.

## *cTnI (Troponin I) Cartridge Test Procedure (Information First Customization)*

1. Press the ⏻ (On/Off) key to turn analyzer on.
2. Press 2 for i-STAT Cartridge from the Test Menu.
3. Scan or Enter Operator ID. Repeat if prompted.
4. Scan or Enter Patient ID. Repeat if prompted.
5. Scan Cartridge Lot number from the cartridge portion pack.
6. Remove cartridge from portion pack. Handle the cartridge by its edges. Avoid touching the contact pads or exerting pressure over the center of the cartridge.
7. Following thorough mixing of the sample, direct the transfer device (either syringe tip or pipette tip) into the inlet port. Apply a single drop of sample to the inlet port. If the cartridge fill is incomplete as seen via the fill indicator on the cartridge label, apply a second small drop until the sample reaches the fill mark.
8. Close the cTnI cartridge:

a. First anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cTnI cartridge from its side edges away from the sample inlet.

b. Use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well. *Note: When sliding the closure clip, the index finger of that same hand should not be placed directly across from the thumb, as this could result in the sample being pushed onto the user's glove. This index finger should be placed just above the position of the sliding clip during closure or not at all.*



9. Insert cartridge into cartridge port. Do not attempt to remove the cartridge while the Cartridge Locked message is displayed.

   *The analyzer must remain on a level surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.*

10. Select tests to be reported, if prompted.
11. Enter sample type on chart page, if applicable.
12. View results on analyzer's display.
13. Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.

3. Press the Print key.
4. Do not move analyzer or printer until printing is complete.

*Printing more than one result*

1. Turn the analyzer on.
2. Press the Menu key.
3. Press 2 for Data Review.
4. Press 7 for List.
5. Scroll through the test records using the ← and → keys.
6. Press the numbered key for the test record(s). (Press the numbered key again to deselect a record.)
7. Align analyzer and printer IR window or place in Downloader or Downloader/Recharger attached to printer. Press the Print key.

### *Transmitting Results*

1. Place analyzer in Downloader or Downloader/Recharger.
2. Do not move analyzer until Communication in Progress message disappears.

## Storage Conditions and Preparation for Use

### *Cartridges*

- Store at temperatures between 2 and 8 °C (35-46°F). Do not use after expiration date on cartridge pouch and box.
- Equilibrate a single cartridge for 5 minutes or a box of cartridges for 1 hour at room temperature before opening pouches.
- Store cartridges for 2 weeks at room temperature. Mark the cartridge box or cartridge pouches with the room temperature expiration date. Do not expose to temperatures above 30 °C (86°F). Do not return cartridges to the refrigerator after room temperature equilibration.
- Use cartridge immediately after removing from pouch.

### *PCx and PCx Plus Glucose Test Strips*

- Store at temperatures between 4 and 30°C (39-86°F). Do not freeze. Keep out of direct sunlight.
- Do not use after expiration date on the barcode label.
- Do not cut the test strip in half or attempt to use only a portion of it.
- After opening foil packet, use test strip promptly.

### *Analyzer*

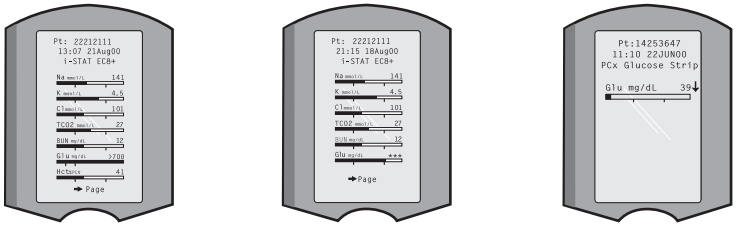
- Storage/Transport temperature: -10 to 46°C (14-115°F)
- The analyzer's operating temperature range is 16 to 30 °C (61-86°F).
- Store analyzers near the testing location or in an area close to the temperature of the testing area. Do not store analyzers near equipment that gives off heat or in direct sunlight.

**Calculated:**

| TEST | UNITS | REPORTABLE RANGE | REFERENCE RANGE (arterial) | REFERENCE RANGE (venous) |
|---|---|---|---|---|
| Hemoglobin/Hb | g/dL<br>g/L<br>mmol/L | 3.4 – 25.5<br>34 – 255<br>2.1 – 15.8 | 12 – 17<br>120 – 170<br>7 – 11 | 12 – 17<br>120 – 170<br>7 – 11 |
| $TCO_2$ | mmol/L (mEq/L) | 1 – 85 | 23 – 27 | 24 – 29 |
| $HCO_3$ | mmol/L (mEq/L) | 1.0 – 85.0 | 22 – 26 | 23 – 28 |
| BE | mmol/L (mEq/L) | (-30) – (+30) | (-2) – (+3) | (-2) – (+3) |
| Anion Gap/AnGap | mmol/L (mEq/L) | (-10) – (+99) | 10 – 20 | 10 – 20 |
| $sO_2$ | % | 0 – 100 | 95 – 98 | |

## *Test Flags and Operator Action*

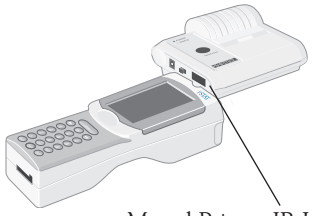
- ***: Results that are not reportable due to sensor errors or interfering substances. Draw a fresh sample and repeat test. If results are flagged again, send sample to the lab.
- < , > and < >: Results that are below or above the reportable range or dependant on results that are outside the reportable range. Send sample to the lab if necessary.
- ↑ and ↓: Results that are above or below the action range. Follow facility procedure for samples with critical values.




## *Printing Test Results*

*Without Downloader or Downloader/Recharger*

1. Turn printer on if green power light is not on.
2. Align IR windows of analyzer and printer.
3. Display results.
4. Press the Print key.
5. Do not move analyzer or printer until printing is complete.
6. If printer is not powered from a wall outlet, turn printer off.




*With Downloader or Downloader/Recharger*

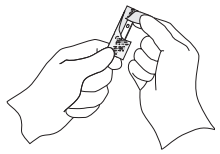
1. Place analyzer in Downloader or Downloader/Rechrager that is wired to the printer.
2. Display results.

## *New Quality Check Codes*

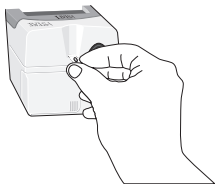
The following are among the new quality check codes for the immunoassay cartridges:

| Error Code | Description |
|---|---|
| 127 | Wet sensor detected before initial sample movement. |
| 128 | Invalid sample type |
| 129 | Analysis fluid mixed with the sample |
| 130 | Air bubble detected in the sample segment |
| 131 | Under-filled cartridge |
| 132 | Air bubble detected in the sample or increased sample size. |
| 140 | Expired cartridge lot. |
| 141 | User failed to scan the cartridge barcode within the allowed period of time. |
| 146 | Overfilled cartridge. |
| 147 | Analyzer not capable of running immunoassay cycles, or not customized properly to run them. |

## *PCx Glucose Test Strip Procedure*



1. Press the ⏻ (On/Off) key to turn the analyzer on.
2. Press 3 for PCx Glucose Strip.
3. Press 1 for Patient.
4. Scan or enter operator ID. Repeat if prompted.
5. Scan or enter patient ID. Repeat if prompted.
6. Scan or enter test strip lot number.
7. Press 1 for Arterial/Capillary or 2 for Venous sample if prompted.



8. Open foil packet, remove test strip and insert into analyzer test strip port with black contact bars facing up and forward.
9. Apply drop of blood to target area of test strip. Cover the entire area. Do not touch the test strip after sample is applied. (If test fails to start after second drop applied or if more than 30 seconds have passed, discard test strip and repeat the test.)

10. Enter chart page information if applicable.
11. View results on analyzer's display.
12. Enter Comment Code if applicable.
13. Remove and discard test strip.
    - Do not handle test strip with wet or dirty hands.
    - Do not scan the barcode of another test strip.
    - Do not use test strips that are wet, scratched or damaged in any way.
    - Do not re-use test strips.

## Scanning

Laser Radiation – Do not stare into beam. Class 2 laser product.
Laser Diode 650 nm Maximum Output 1.0 mW.

1 Press and hold down the Scan key to start the barcode scanner. The analyzer emits a visible red beam.

2 Position the analyzer and barcode so the beam forms a red line that spans the entire barcode. Increasing distance between the barcode and analyzer lengthens the red line. The analyzer does not need to touch the barcode.

3 When the analyzer accepts the barcode, it will beep in acknowledgement and automatically turn off the beam. The beam will also turn off after 3 seconds.

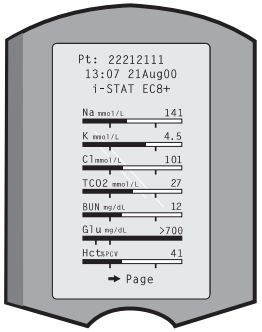
4 View the data that was scanned by the analyzer and verify that it is correct.

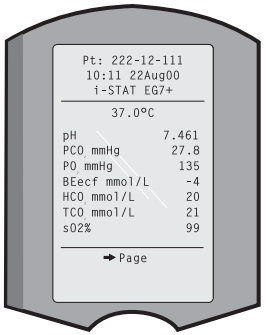
5 Release the Scan key.

**Note:** If the Scan key is released as soon as the beep is heard, the next prompt will be displayed and the information scanned will not be able to be viewed.

## Reviewing Test Results

- The 0 key can be used to backlight the display to view results in dim lighting. (The backlight turns off after 90 seconds or when the 0 key is pressed again.)
- Test results are displayed numerically and with bar graphs. Tick marks indicate the reference ranges on the bar graphs. (Blood gases and their associated calculated values are not displayed with bar graphs and reference ranges.)
- Test results are displayed for 2 minutes or a customized time. To recall the last set of results to the screen, turn the analyzer on and press 1 for Last Result.
- To review results from the same patient, when results are displayed, press 1 for Test Options and then 3 for History. Scroll through test records using the 1 and 2 keys.
- To review another patient's results, turn the analyzer on and press the Menu key followed by the 2 key for Data Review and the 1 key for patient. Scan or enter the Patient's ID number. Use the 1 and 2 keys to scroll through the test records. Or, press the Menu key followed by the 7 key for List. Select the test record(s) to be reviewed and press the Enter key.




## Reportable and Reference Range

### Measured:

| TEST | UNITS | REPORTABLE RANGE | REFERENCE RANGE (arterial) | REFERENCE RANGE (venous) |
|---|---|---|---|---|
| Sodium/Na | mmol/L (mEq/L) | 100 – 180 | 138 – 146 | 138 – 146 |
| Potassium/K | mmol/L (mEq/L) | 2.0 – 9.0 | 3.5 – 4.9 | 3.5 – 4.9 |
| Chloride/Cl | mmol/L (mEq/L) | 65 – 140 | 98 – 109 | 98 – 109 |
| Glucose/Glu | mmol/L<br>mg/dL<br>g/L | 1.1 – 38.9<br>20 – 700<br>0.20 – 7.00 | 3.9 – 5.8<br>70 – 105<br>0.70 – 1.05 | 3.9 – 5.8<br>70 – 105<br>0.70 – 1.05 |
| Lactate/Lac | mmol/L<br>mg/dL | 0.30 – 20.00<br>2.7 – 180.2 | 0.36 – 1.25<br>3.2 – 11.3 | 0.90 – 1.70<br>8.1 – 15.3 |
| Creatinine/Crea | mg/dL<br>µmol/L | 0.2 – 20.0<br>18 – 1768 | 0.6 – 1.3<br>53 – 115 | 0.6 – 1.3<br>53 – 115 |
| pH | | 6.5 – 8.0 | 7.35 – 7.45 | 7.31 – 7.41 |
| $PCO_2$ | mmHg<br>kPa | 5 – 130<br>0.67 – 17.33 | 35 – 45<br>4.67 – 6.00 | 41 – 51<br>5.47 – 6.80 |
| $PO_2$ | mmHg<br>kPa | 5 – 800<br>0.7 – 106.6 | 80 – 105<br>10.7 – 14.0 | |
| Ionized Calcium/iCa | mmol/L<br>mg/dL | 0.25 – 2.50<br>1.0 – 10.0 | 1.12 – 1.32<br>4.5 – 5.3 | 1.12 – 1.32<br>4.5 – 5.3 |
| Urea Nitrogen/BUN<br>Urea | mg/dL<br>mmol/L<br>mg/dL | 3 – 140<br>1 – 50<br>6 – 300 | 8 – 26<br>2.9 – 9.4<br>17 – 56 | 8 – 26<br>2.9 – 9.4<br>17 – 56 |
| Hematocrit/Hct | %PCV<br>Fraction | 10 – 75<br>0.10 – 0.75 | 38 – 51<br>0.38 – 0.51 | 38 – 51<br>0.38 – 0.51 |
| Celite Activated Clotting Time / Celite ACT | seconds | 50 – 1000 | 74 – 125 (Prewrm)<br>84 – 139 (Nonwrm) | 74 – 125 (Prewrm)<br>84 – 139 (Nonwrm) |
| *The range from 80 - 1000 seconds has been verified through method comparison studies.* | | | | |
| Kaolin Activated Clotting Time / Kaolin ACT | seconds | 50 – 1000 | 74 – 137 (Prewrm)<br>82 – 152 (Nonwrm) | 74 – 137 (Prewrm)<br>82 – 152 (Nonwrm) |
| *The range from 77 - 1000 seconds has been verified through method comparison studies.* | | | | |
| Prothrombin Time / PT | INR | 0.9 – 8.0 | | |
| *Performance characteristics have not been established for INRs above 6.0.* | | | | |
| Troponin I / cTnI | ng/mL (µg/L) | 0.00 – 50.00 | | 0.00 – 0.03* |
| *Performance characteristics have not been established for cTnI values above 35.00 ng/mL.*<br>** Represents the 0 to 97.5% range of results.* | | | | |

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